PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label Text

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BIMOTRIM CO INJECTION
Solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Concentration: A clear, sterile, aqueous solution for parenteral administration, containing in each ml 200 mg Sulfadoxine Ph Eur, 40 mg Trimethoprim Ph Eur and 1 mg Sodium Formaldehyde Sulfoxylate as antioxidant.

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

100ml

5. TARGET SPECIES

CATTLE AND HORSES

6. INDICATION(S)

Indications for Use: The *in vitro* activity covers most common Gram-positive and Gram-negative bacteria including: *Actinobacillus* spp., *Actinomyces bovis*, *Bordetella* spp. *Corynebacterium* spp., *Klebsiella* spp., *Listeria monocytogenes*, *Nocardia* spp., *Pasteurella* spp., *Proteus* spp., *Salmonella* spp., *Staphylococcus* spp., and *Streptococcus* spp**.**

The injection may be used in the treatment of a wide range of diseases and conditions of bacterial origin in cattle and horses. Respiratory infections of bacterial origin including pneumonia, rhinitis, bronchitis and secondary bacterial infections following virus pneumonia or mycoplasmal infections. Urogenital tract infections including cystitis, vaginitis, urethritis, nephritis and metritis. Alimentary tract infections, neonatal diarrhoea, salmonellosis and post-weaning enteritis.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dosage and Administration: Dose: 15mg/kg.
1 ml per 16 kg bodyweight daily. Daily dosing should be repeated for two days after symptoms have resolved up to a maximum of 5 days.
Cattle: By slow intravenous or intramuscular injection. Intramuscular injection is the preferred route and should be given into the neck.
Horses: By slow intravenous injection over as long a period as is reasonably practical.

8. WITHDRAWAL PERIOD

Withdrawal Period: Cattle: Milk: 60 hours. Meat & offal: 10 days.
Horses: Not to be used in horses intended for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Contra-indications, Warnings etc: Please refer to package leaflet.
Do not administer by the intraperitoneal or subcutaneous route.
Intravenous injections should be administered slowly over as long a period as is reasonably practical.
Do not administer to horses exhibiting cardiac arrhythmias. Such arrhythmias may be associated with the administration of certain anaesthetic and sedative agents.
Do not exceed the recommended dose or treat animals for more than 5 consecutive days.

10. EXPIRY DATE

Expiry Date:

Once broached use by: / /

11. SPECIAL STORAGE CONDITIONS

DO NOT STORE ABOVE 25°C.
DO NOT FREEZE.
PROTECT FROM LIGHT.

Pharmaceutical precautions: Following withdrawal of the first dose, use the product within 28 days.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

FOR ANIMAL TREATMENT ONLY.
To be supplied only on veterinary prescription. POM- V

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
2 / 3 / 4 Airton Close
Tallaght
Dublin 24
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 50146/4027

17. MANUFACTURER'S BATCH NUMBER

Batch No:

PACKAGE LEAFLET

Bimotrim Co Injection, Solution For Injection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Bimeda Animal Health Limited
2 / 3 / 4 Airton Close
Tallaght
Dublin 24
Ireland

Manufacturers:
Bimeda Chemicals Ltd.
Broomhill Road
Tallaght
Dublin 24
Ireland

Ballinskelligs Veterinary Products Ltd
Ballinskelligs
Killarny
Co. Kerry
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimotrim Co Injection, Solution for Injection

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Active Substance	
Sulfadoxine	200 mg/ml
Trimethoprim	40 mg/ml
Excipients	
Sodium Formaldehyde Sulphoxylate	1mg/ml (Antioxidant)

4. INDICATIONS

The in *vitro* activity covers most common Gram-positive and Gram-negative bacteria including *Actinobacillus* spp., *Actinomyces bovis*, *Bordetella* spp., *Corynebacterium* spp., *Klebsiella* spp., *Listeria monocytogenes*, *Nocardia* spp., *Pasteurella* spp., *Proteus* spp., *Salmonella* spp., *Staphylococcus* spp., and *Streptococcus* spp.

Indications: The injection may be used in the treatment of a wide range of diseases and conditions of bacterial origin in cattle and horses. Respiratory

infections of bacterial origin including pneumonia, rhinitis, bronchitis and secondary bacterial infections following virus pneumonia mycoplasmal infections. Urogenital tract infections including cystitis, vaginitis, urethritis, nephritis and metritis. Alimentary tract infections, neonatal diarrhoea, salmonellosis and post- weaning enteritis.

5. CONTRAINDICATIONS

Do not administer by the intraperitoneal or subcutaneous route.
Do not administer to horses exhibiting cardiac arrhythmias. Such arrhythmias may be associated with the administration of certain anaesthetic and sedative agents.

6. ADVERSE REACTIONS

Very occasionally, temporary irritating swellings may appear at the site of injection.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle and horses

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dose: 15mg/kg (equivalent to 1 ml per 16 kg bodyweight) daily. Daily dosing should be repeated for two days after symptoms have resolved up to a maximum of 5 days. Do not exceed the recommended dose or treat animals for more than 5 consecutive days.

Route of administration:
Cattle: By slow intravenous or intramuscular injection. Intramuscular injection is the preferred route and should be given into the neck.
Horses: By slow intravenous injection.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD

Cattle: Meat & offal: 10 days. Milk: 60 hours
Horses: Not to be used in horses intended for human consumption.
Treated horses may never be slaughtered for human consumption.
The horse must have been declared as not intended for human consumption under national horse passport legislation.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not freeze. Do not store above 25°C. Protect from light.
Following withdrawal of the first dose use the product within 28 days.
Do not use after the expiry date stated on the label.
Discard unused material.

12. SPECIAL WARNINGS

Special precautions for use in animals

The following warnings are applicable to all Trimethoprim Sulfonamide combinations for use in the horse.

1. Cardiac and respiratory shocks in horses have been observed, mostly after intravenous injection.
2. The injection solution should be approximately at body temperature. At the first signs of intolerance, the injection should be interrupted and shock treatment initiated. The product should be injected slowly over as long a period as is reasonably practical.
3. The intravenous route of administration is contra-indicated in the case of previous or concurrent administration of central nervous system depressants (e.g. anaesthetics, neuroleptics).
4. The possibility of an anaphylactic or hypersensitivity reaction occurring following administration on rare occasions must be borne in mind.
5. As with all trimethoprim sulphonamide formulations the possibility of potential damage to the kidney or liver or haematopoetic system should be considered.

User Warnings

Care should be taken to avoid accidental injection and contact with the skin.
Wash hands after use.
Sulphonamides may cause hypersensitivity (allergy) following, injection, inhalation, ingestion or skin contact. Hypersensitivity to sulphonamides may lead to cross reactions with other antibiotics. Allergic reactions to these substances may occasionally be serious.
Do not handle this product if you know you are sensitive to sulphonamides.
If you develop symptoms following exposure such as skin rash, you should seek medical advice and show the doctor this warning.

Use during pregnancy and lactation

Studies during pregnancy have not been conducted. Use with care in pregnant animals.

Interaction with other medicinal products and other forms of interactions

Because of the competitive action of the sulphonamides, their activity may be antagonised by the presence of any of the following:

1. Para-Aminobenzoic acid (PABA) and related compounds, particularly local anaesthetics with a PABA nucleus such as procaine, butacaine and benzocaine, but also compounds associated with those such as procaine penicillin. It is recommended that local anaesthetics of the procaine group should not be used during treatment with Bimotrim Co Injection.
2. Some members of the Vitamin B complex, such as nicotinamide, folic acid, choline and precursors of these.
3. Proteins which combine loosely with the sulphonamides and at least temporarily reduce their antibacterial activity. Gelatin, albumin, peptone and serum protein all antagonise the sulphonamides. Associated with this group are products of cell and tissue death, especially pus, which also acts as a non-vascular, mechanical barrier.
4. A number of other compounds, including enzymes, glucose and mercuric chloride, are all reported to have antagonistic effects against sulphonamides.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2019

15. OTHER INFORMATION

POM-V Prescription only Medicine
To be supplied only on veterinary prescription.
UK authorised veterinary medicinal product.
MA No. Vm 50146/4027
Package Quantities: Multidose vials of 100 ml.

Distributed by:
Bimeda ®
Cross Vetpharm Group UK Ltd.
Unit 2, Bryn Cefni
Llangefni
Anglesey
LL77 7XA
United Kingdom

FOR ANIMAL TREATMENT ONLY

Approved: 24 July 2019